IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LOREM VASCULAR, Pte. Ltd., a Singapore Company, Plaintiff, v. PLUS THERAPEUTICS, INC. f/k/a CYTORI THERAPEUTICS, INC., a Delaware corporation; and DOES 1 through 30, inclusive, Defendants.	)	C.A. No. **JURY TRIAL DEMANDED**

COMPLAINT FOR (1) BREACH OF CONTRACT; (2) BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING; (3) FRAUDULENT INDUCEMENT; AND (4) NEGLIGENT MISREPRESENTATION

Plaintiff Lorem Vascular, Pte. Ltd. ("Lorem") brings this complaint against Defendant Plus Therapeutics, Inc. f/k/a Cytori Therapeutics, Inc. ("Plus") and Does 1-30 (collectively "Defendants") and alleges as follows:

INTRODUCTION

1. By this action, Lorem alleges that Plus intentionally and fraudulently induced Lorem to enter into an Asset and Equity Purchase Agreement ("APA") dated March 29, 2019, by falsely and deceitfully representing that Plus's manufacturing facility in the United Kingdom was certified to manufacture, sell and distribute medical devices in the European Union and to export such devices to China, when in fact such representations were knowingly and intentionally false when made, and when in fact Cytori UK's facility was not so certified by the European Union notifying body BSI.

2. Prior to entering into the APA, Lorem had exclusively licensed all marketing, sales, and distribution rights from Plus in 2014 for the products of the business (Celution cell therapy

technology) for China, Hong Kong, Singapore, Malaysia and Australia for a period of thirty years. As part of that prior license, Plus was the supplier of products to Lorem and Plus was required to establish and subsequently did establish a Conformité Européenne (French for "European Conformity") or "CE" certified product manufacturing facility in the United Kingdom to enable the appropriate and/or authorized regulatory status of products in China. This was known by all parties to be essential to Lorem's business at all times from the inception of their relationship in 2014 to the date of the APA.

3. In fact, in one of Lorem's early term sheets for the APA dated June 26, 2018, Lorem specifically indicated to Plus in Appendix B that "The Deeside facility must be able to **legally ship products to China** under our current Class I filing in the same way that Cytori was able to ship products into China in 2016 from Deeside" (emphasis in original). Again, on August 19, 2018, Lorem specifically informed Plus that CE certification was a "deal breaker."

4. Plus specifically misrepresented (verbally, in documents presented to Lorem immediately prior to the APA, and in the disclosure schedules to the APA) that the certification status of its UK facility (the most critical of the assets Lorem was to acquire) was intact, but for the completion of a routine annual audit costing relatively little in terms of time (1 to 2 weeks) and money ($8,000). In fact, on April 8, 2019 (over a week after the APA was signed but sixteen days before closing), the data room maintained by Cytori for due diligence materials for the APA specifically confirmed "suspensions or cancellations (NONE)" (capitalization in original).

5. The true and undisclosed facts, however, were that Cytori UK's certification was knowingly and intentionally canceled by Plus executive management in 2018, that Plus's canceled certification could not be reactivated with a routine audit, and that Lorem would instead have to restart the entire certification process all over from scratch, a stringent and laborious process that

would take years and cost many hundreds of thousands if not millions of dollars, to say nothing of the lost production, and loss of regulatory status and activities in other countries that depend on the Certification in the interim. In fact, in an August 3, 2018 letter from Farah Khan of BSI Group to Terrie Heidemann at Cytori, Ms. Khan thanked Ms. Heidemann "for notifying BSI of the *Senior Management decision of Cytori Ltd. to cancel the above CE certificates* for Cytori Ltd. held with BSI [CE 619294 & CE 622786, the two CE certificates for the Cytori UK facility]." (emphasis added).

6. Plus knew the lack of CE certification in the UK was a deal-breaker, which is why Plus not only hid these crucial facts, but went so far as to fraudulently maintain lapsed certificates in the data room for the deal, on the false pretense that a minor audit remained to be performed. If Lorem had known the true facts and had known prior to closing that Cytori UK's certification had been canceled and that Lorem would have to restart the entire certification process all over from scratch, then Lorem would never have consummated the APA.

THE PARTIES

7. Lorem is a regenerative medicine company offering clinical-grade autologous regenerative cell therapy to treat a variety of vascular and non-vascular diseases. Lorem is a corporation formed under the laws of Singapore with its principal place of business in Singapore.

8. Plus is a clinical-stage pharmaceutical company focused on developing therapies for rare cancers. Plus is a corporation formed under the laws of Delaware with its principal place of business in Austin, Texas.

9. The true names and capacities, whether individual, corporate, associate, partnership or otherwise, of Defendants Does 1 through 30, inclusive, and each of them, are unknown to Lorem

who therefore sues said Defendants by such fictitious names. Lorem will amend this complaint to allege the true names and capacities of such Defendants when ascertained.

10. At all relevant times, Defendants, and each of them, were the agents, employees, fiduciaries, representatives, partners or co-venturers of the other Defendants, and each of them, and in doing the things herein alleged, were acting for the purpose and within the course, scope and authority of such agency, employment, fiduciary, partnership and co-venturer relationship.

11. At all relevant times, Defendants, and each of them, were completely dominated and controlled by the other Defendants, and each of them, such that Defendants have no independent identity or existence of their own and their acts were the acts of the other Defendants, and each of them, such that adherence to the purported separate identities of each or any of them would result in a fraud and injustice to Lorem.

JURISDICTION AND VENUE

12. Jurisdiction is proper under 28 U.S.C. § 1332 because Lorem is a citizen of Singapore and Plus is a citizen of Delaware and Texas and the amount in controversy exceeds $75,000. Venue is proper under 28 U.S.C. § 1391 because, by virtue of its incorporation under Delaware law, Plus is a citizen of Delaware. Jurisdiction and venue are also proper in this Court pursuant to Section 11.11 of the APA, which provides in pertinent part that "[t]his Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware. All Actions arising out of or relating to this Agreement shall be heard and determined exclusively in any federal court sitting in Delaware; provided, however, if such federal court does not have jurisdiction over such Action, such Action shall be heard and determined exclusively in any Delaware court sitting in Delaware."

FACTUAL BACKGROUND

A. Brief Overview of Medical Device Certifications

13. The parties are in the medical device business, and the primary assets purchased by Lorem under the APA were Plus's Celution cell processing systems and devices that were designed, developed and manufactured by Plus Therapeutics, including the Celution consumable set, Celase reagent and Intravase reagent. In 1994, the European Union ("EU") introduced the Medical Device Directive ("MDD") to regulate medical devices sold in the EU. The MDD is based on the principles of the "New Approach to Technical Harmonization and Standards," a set of regulations in the EU that standardizes technical requirements, testing and certification procedures.

14. A Conformité Européenne (French for "European Conformity") or "CE" certificate is a certificate issued and renewed annually by a regulatory authority (*e.g.*, BSI Group) that a manufacturer's product meets all relevant MDD regulations, which prescribe rigorous safety and performance requirements for the marketing and sale of medical devices in the EU. A CE certificate is legally required before an EU entity can sell medical devices (including Class IIa, IIb, and III devices) in the EU (place on the market) or export its products abroad. There are numerous and complex rules and procedures that must be followed in order to obtain and maintain CE certification, beginning with the proper classification of the medical device or biomedical product at issue and selection of the appropriate conformity assessment route to follow for each particular medical device or product.

15. Select countries outside of the EU (including China) allow for an abbreviated regulatory review when a device is manufactured and certified in the EU, and a Free Sale Certificate is issued by a regulatory authority in the country (EU Member State) where the device

is manufactured (country of origin). The Free Sale Certificate is issued to the manufacturer on the basis of the existence of a valid CE Certificate for the device. The Free Sale Certificate is the primary instrument used to demonstrate that the device is legally available in the country in which it is manufactured (country of origin). When such an arrangement is made for device approval in a non-EU country, the CE certifications allow companies holding CE certificates in the EU to export and sell their medical devices in those countries. China is one such foreign country that will allow foreign companies to import and market certain medical devices in China provided they are allowed to freely sell such products in the country of manufacture (country of origin). This is accomplished by providing the regulatory authorities in China with a Free Sale Certificate.

16. A valid CE certificate for the Class IIa, Class IIb and Class III products issued to the manufacturer Cytori Ltd. in the EU is necessary to support the Free Sale Certificate for importation of the Celution medical devices into China. These are the products that Lorem justifiably expected to be able to export from Cytori Ltd. in the UK to China pursuant to the APA. Only weeks prior to the APA, Plus manufactured, sold and exported these same products to Lorem in China from Cytori Ltd. However, the CE Certificate was invalid (cancelled), and therefore the Free Sale Certificate (which is based on the CE Certificate), would then also be invalid, as would the Chinese regulatory approval based on the Free Sale Certificate. Taken in the inverse, a Free Sale Certificate for such products could not and would not be issued by a regulatory authority in an EU Member State when the CE Certificate was not valid. Furthermore, the Certificate of Free Sale for export of products into China specifically indicates that the products are CE marked and "may be freely sold in all member states." When Plus manufactured, sold and exported a batch of the Class IIa and Class IIb products from its Cytori Ltd. UK facility to Lorem in China on March 20, 2019 just prior to the APA, it was done based on Free Sale Certificates that were no longer

valid on their face because the declaration supporting the Free Sale Certificate (*i.e.*, Mark Hedrick's December 5, 2014 declaration of qualification for Certificate of Free Sale) was no longer true, and the CE Certification no longer existed.

17. Since its introduction in 1994, the MDD was regularly updated to ensure consistency with ever-changing EU standards. In 2020, however, the MDD was scheduled to be replaced by the more stringent Medical Device Regulation ("MDR"), which prescribes (among other things) stricter information requirements for registration and conformity assessments, brand new Unique Device Identification ("UDI") requirements, greater post-marketing surveillance ("PMS") of certified products, including regular PMS reporting depending on the class of the device, and technical and procedural requirements and controls that are more strict than those under the MDD. MDR certification and compliance will be much more time-consuming and much more expensive than MDD certification and compliance. Further complications with the MDR certification process include the fact that there is a significant decline in the number of Notified Bodies certified by the European Commission to issue MDR certificates. The limited number of MDR qualified Notified Bodies creates significantly longer timelines, as medical device companies move from their previous Notified Bodies to the few Notified Bodies that can issue MDR certificates. Lorem's regulatory strategy for China was based entirely on using the existing CE Certification supplied by Plus to sell the Products in China immediately, and to seek expansion of the Claims in the EU to leverage these and existing claims with the Chinese regulatory officials to speed up and simplify future approvals. The whole business strategy of Lorem was based upon the existence of a CE Certified Cytori Ltd.

B. Plus's Repeated Misrepresentations As To The Status Of Cytori UK's CE Certification

18. In 2018, the parties began discussions to acquire Plus's Celution cell processing device and related products and assets. Beginning in or about February, 2019, Plus provided Lorem electronic access to many key documents relating to the acquisition through an online Data Room. The Data Room recorded each viewing and downloading of the documents that were provided to Lorem. The Data Room time and date stamps each document pulled from the data room, identifying the person viewing or downloading the file. Among many other business documents, the Data Room included a copy of the CE Certificate for Cytori Ltd. facility in the U.K. (valid on its face through the end of 2019) which attests that Cytori Ltd. was CE compliant. This Certificate was made available to, and provided to Lorem (without qualification as to its validity) from February 2019 through April 2019. The CE Certificate attests to the "design, development, manufacture and final inspection of the Celution 800 Cell Processing Device, Celution 805 Consumable Set, Celase reagent and Intravase reagent" (a true and correct copy of which is attached hereto as Exhibit A. At no time prior to or after the closing of the APA did Plus discuss, reference, disclose or provide Lorem a copy of the Notice of Termination of the CE Certificate for Cytori Ltd.

19. At all relevant times during the negotiation process, Plus's officers and directors (including Tiago Girão) represented verbally and in writing that Cytori UK's facility was CE compliant, which was consistent with its CE certificate in the Data Room. These misrepresentations include the following:

i. Cytori presented CE Certificates for Cytori Ltd. to Lorem (namely, CE 619294 and CE 622786) that appeared valid on their face without any notice of suspension or termination;

ii. Cytori represented and warranted in Section 3.10 of the Disclosure Schedule to the APA that Cytori was "Not in compliance: Last year, the Company was supposed to perform an audit of the UK facility last year. This has not been done yet. As a result, Inventory assembled in the UK facility cannot be exported to the UK or EU," which intentionally created the false impression upon Lorem that the only reason why Cytori UK was not in compliance was because it had not yet completed an audit that was due in 2017, a routine and perfunctory process that takes a few weeks and costs little (*e.g.*, $8,000), and that once Lorem completed the overdue audit after the APA CE compliance would be restored;

iii. On or about March 26, 2019, pursuant to Lorem's purchase order, Cytori shipped 84 Celution 805IV Consumable Sets (0815-10) and 84 vials of Celase 35mg from Cytori's UK facility in Deeside to Lorem's facility in Beijing, China and invoiced Lorem accordingly for $46,200, and $21,000, respectively, which confirmed to Lorem that a valid CE Certificate existed for Cytori's Deeside facility because otherwise the exportation would have been illegal (true and correct copies of Cytori's invoices to Lorem are attached hereto as Exhibit B);

iv. On or about March 26, 2019, on a teleconference between Tiago Girão and Cytori's attorney with Lorem representatives Mr. Kleinhenz and Mr. Soneff, Mr. Girão read aloud a proposed disclosure for Schedule 3.10(b) that may have effectively excused any failure of the European regulatory status representation and warranty for Cytori UK as it relates to the Products. Mr. Soneff and Mr. Kleinhenz rejected the proposed language and re-asserted Lorem's position that there could be no APA transaction without valid CE Mark Certification for Cytori UK;

v. Mr. Soneff and Mr. Kleinhenz (as well as Mr. KT Lim) each recall verbal confirmations from Mr. Girão that Cytori UK was CE Certified leading up to the APA. Neither of them was ever told by Plus that the CE Certification for Cytori UK had been canceled. Lorem had requested documentation for the regulatory audit of Cytori UK multiple times leading up to execution of the Agreement, and Mr. Girão informed Mr. Soneff and Mr. Kleinhenz that such documentation would be forthcoming. Just prior to signing the APA, Cytori confirmed that the Cytori UK audit had not yet occurred in the Disclosure Schedule, and that it would be necessary to complete before resuming operations. Completing the audit is understood to be a routine and relatively straightforward matter to correct, so this was not viewed as material.

20. However, as alleged more fully herein, Plus's representations that Cytori UK was CE Certified were knowingly and intentionally false and misleading when made. Since the APA was entered into, Lorem has discovered the following facts, all of which were unbeknownst to it at the time:

(i) Lorem is informed and believes that on or about November 29, 2017, Cytori UK notified third-party BSI (who is a Notifying Body under the MDD and who conducts audits and issues CE certificates under the MDD and MDR) that it had suspended operations at its Deeside facility as a result of which surveillance and audits could not be performed by BSI. Accordingly, Cytori UK's CE certification was suspended by BSI on January 12, 2018 (a true and correct copy of the suspension letter is attached hereto as Exhibit C). After several attempts by BSI to schedule audits at Deeside over the next eight months, Plus informed BSI that Cytori UK senior management (including Dr. Mark Hedrick and Tiago Girão) intentionally approved the cancellation of Cytori UK's CE Certificate at Deeside, which BSI confirmed to Plus by letter dated August 3, 2018 (a true and correct copy of which is attached hereto as Exhibit D). On information

and belief, Plus was officially notified of the cancellation by letter dated on or about August 10, 2018.

(ii) Because Cytori UK's CE certificates were intentionally canceled by its own senior management, on information and belief, BSI informed Plus that the original certificates could no longer be reinstated as own brand labeler ("OBL")[1] certificates by completing an audit but would instead need to be applied for de novo and converted into the new MDR Annex II certificates, which would require a completely new and uncertain CE certification process to be completed, a process that on information and belief takes multiple years and costs upwards of millions of dollars to complete, with no guarantee of success.

(iii) On or about August 10, 2018, Plus received a cancellation letter confirming that Cytori UK was no longer CE Certified per the express request of Cytori Management.

21. At no time during the negotiation process, however, or at any time prior to closing of the APA, did Plus reference, discuss, or provide Lorem with the suspension notice or the cancellation letter, or in any way reference the prior cancellation of the CE Certificates. As such, Lorem is informed and believes that Plus's representations that Cytori UK's facility was CE certified were made fraudulently, knowingly, willfully, and/or negligently in order to induce Lorem to execute the APA.

22. Throughout the negotiation and drafting of the APA, Plus was highly-motivated to misrepresent the true facts and do whatever it took to execute the APA by March 29, 2019 (and

[1] An own brand labeler ("OBL") is a company that sells or distributes another manufacturer's device under its own brand name, as opposed to the brand name of the Original Equipment Manufacturer ("OEM"). Cytori Ltd. completed some of the manufacturing process in its facilities sufficient to be deemed the OBL manufacturer. CE certificates held by OBLs are sometimes referred to interchangeably as OBL or CE certificates.

not a day later). On information and belief, Plus's lender required that Plus enter into an asset purchase and sale agreement by March 29, 2019 under which Plus would receive at least $4 million in unrestricted cash. On information belief, there were three such agreements with Plus's lenders and the March 29, 2019 date was reputed to be the last such date. That is why the effective date of the APA is March 29, 2019 even though Lorem did not release its signatures until late on March 30, 2019 and the APA did not close until April 24, 2019. In view of the enormous financial pressure Plus was facing (and potential forced liquidation), Plus was highly-motivated to make (and did make) misleading statements to Lorem regarding the CE compliance of its Deeside facility (or lack thereof) in order to ensure that the APA would be executed by March 29, 2019 without further delay. Indeed, Plus's Form 8-K dated March 5, 2019 explicitly stated (among other things) that:

> "On March 4, 2019, Cytori Therapeutics, Inc. (the 'Company') entered into an amendment, effective as of February 28, 2019 (the 'Amendment'), to its existing Loan and Security Agreement, dated May 29, 2015, as amended (the 'Loan Agreement'), with Oxford Finance LLC ('Oxford'), as collateral agent, and the lenders party thereto, including Oxford (the 'Lenders'), pursuant to which, among other things, Oxford and the Lenders agreed to extend requirements that the Company achieve one of the following by March 29, 2019: enter into an asset sale agreement with a minimum unrestricted net cash proceeds to the Company of $4.0 million; enter into a binding agreement for the issuance and sale of its equity securities or unsecured convertible subordinated debt which would result in unrestricted gross cash proceeds of not less than $7.5 million; or enter into a merger agreement pursuant which the obligations under the Loan Agreement would be

paid down to a level satisfactory to Oxford and the Lenders." (A true and correct copy of this Form 8-K is attached hereto as Exhibit E).

23. Plus also knew that Lorem would detrimentally rely on these misrepresentations, misrepresentations that were fundamentally critical to Lorem's decision as to whether to proceed with the APA. At all material times leading up to and through the acquisition, Lorem informed Plus that it was essential to the APA that the Cytori UK facility be CE certified in order for Lorem to continue exporting products from the UK to China. For example, in a letter dated June 25, 2018, Lorem informed Plus (among other things) that the "Deeside facility must be able to **legally ship products to China** under our current Class I filing in the same way that Cytori was able to ship products into China in 2016 from Deeside. This means the Deeside facility must be ISO 13485 certified and that Cytori Ltd UK must hold an MDD Annex II certificate for the Celution System . . ." (emphasis in original). Lorem reiterated this requirement in numerous Term Sheets to Cytori.

24. Indeed, Cytori UK's CE certified status was so critically important to Lorem that some of Lorem's early term sheets submitted to Plus prior to the APA indicated Lorem's intent to purchase only the Cytori UK facility, provided of course that it maintained its CE compliance.

25. In March 2019, as the closing date of the APA was approaching and as part of its due diligence, Lorem placed a purchase order for 84 consumable sets and 84 vials of Celase products from Plus to be exported from Cytori UK to Lorem's facilities in Beijing, China. Plus accepted and fulfilled Lorem's purchase order and exported the products to Lorem in China, thus bolstering its deception to Lorem that Plus's CE certificate for Cytori UK was valid, when in fact it was not.

26. On March 29, 2019, *less than 24 hours* before the parties signed the APA, Plus provided a revised Section 3.10(b) Disclosure Schedule to Lorem, which appears to have been a

direct result of the March 28, 2019 telephone conversation between Tiago Girão, Jon Soneff and Ken Kleinhenz. Section 3.10(b) of the Disclosure Schedule provides (among other things) that "[t]he certificates included in Exhibit 3.10(b) to these schedules" (including the CE Certificate for Cytori UK) were "Not in compliance: Last year, the Company [Plus] was supposed to perform an audit of the UK facility last year. This has not been done yet. As a result, Inventory assembled in the UK facility cannot be exported to the UK or EU."

27. This disclosure in Section 3.10, however, was false and highly-misleading because it falsely indicates that the CE certification for Cytori UK was intact and that the only action needed for the Cytori UK's CE certificate to be reinstated to compliance was to conduct an overdue audit that "had not been done yet." Such an audit was a perfunctory annual requirement that typically takes only a few weeks and costs relatively little ($8,000). This false representation, together with the seemingly valid CE Certificates presented, and Plus's shipment of Product from Cytori UK to Lorem's facilities in China, embroidered upon Plus's repeated assurances by Mr. Girão throughout the negotiation of the APA that Cytori UK was in good standing and that the CE Certification was intact, further ensured that Lorem would not unravel the deception prior to signing the APA.

28. As alleged above, however, the true and undisclosed facts were that Plus's senior management had intentionally canceled the CE certificates for the Cytori UK facility in August 2018, that because of the intentional cancellation the CE certificates could not be restored or reinstated with the customary annual audit, and that instead Lorem would need to restart the entire CE certification process over from scratch, a process that would take one and a half to two plus years (if at all achievable) and cost hundreds of thousands if not millions of dollars, with no guarantee of success.

29. Plus's deception proved successful, and on April 24, 2019, the parties closed the APA.

30. If Lorem had known the true facts prior to closing—that Cytori UK's CE certificate had been canceled, and that Lorem would have to restart the entire CE certification process all over from scratch—Lorem would never have consummated the APA.

C. The Asset and Equity Purchase Agreement (APA)

31. Under the March 29, 2019 APA, Lorem essentially acquired all of Plus's assets associated with its cell therapy business in exchange for approximately $3,000,000 (in addition to the payment of approximately $1,000,000 in debt owed by Cytori UK to Plus). The APA included numerous material terms and representations. In the APA, Plus represented and warranted, among other things, that:

(i) Plus was "in good standing under the laws of the jurisdiction of its incorporation" and was authorized to "conduct its business as it is now being conducted" (APA, Section 3.01);

(ii) Plus's Books and Records[2] were "complete and accurate in all material respects" (APA, Section 3.06);

(iii) Plus's "Business and the business of Cytori UK has been conducted in the Ordinary Course of Business" and that there has not occurred any "material damage, destruction or loss, of any material interruption in use, of any Purchased Assets, whether or not covered by insurance, or any changes in the amount or scope of insurance coverage" (APA, Section 3.08);

[2]Unless otherwise noted, capitalized terms have the same meaning as in the APA.

(iv) Plus "(i) has "conducted and continues to conduct its business in accordance with all Laws and Governmental Orders applicable to the Business in all material respects;" (ii) neither Seller nor Cytori UK is in material violation of any such Law or Governmental Order, including, all applicable laws (including regulations, rules, guidance, and policies) promulgated by the FDA or any other Governmental Authority relating to Current Good Manufacturing Practice, quality systems, medical device reporting, device design, establishment registration and product listing, tracking (as applicable), product export, unique device registration and post market surveillance regulations; and (iii) no event has occurred or circumstances exist that (with or without notice or lapse of time) may constitute or result in a material violation by Seller or Cytori UK of, or a material failure of Seller or Cytori UK to comply with, any Law with respect to the Purchased Assets or the Business" (APA, Section 3.10(a));

(v) "Section 3.10(b) of the Disclosure Schedule purported to contain a complete and accurate list of each Permit related to the Business held by Seller and Cytori UK. Each Permit listed or required to be listed in Section 3.10(b) of the Disclosure Schedule is valid and in full force and effect. Except as set forth in Section 3.10(b) of the Disclosure Schedule, (i) Seller (or, as applicable, Cytori UK) is and has been since the Reference Date, in full compliance with all of the material terms and requirements of each Permit identified or required to be identified in Section 3.10(b) of the Disclosure Schedule; (ii) no event has occurred or circumstance exists that may (with or without notice of lapse of time) (A) constitute or result directly or indirectly in a violation of or a failure to comply with any material term or requirement of any Permit listed or required to be listed in Section 3.10(b) of the Disclosure Schedule or (B) result directly or indirectly in the revocation, withdrawal, suspension, cancellation or termination of, or any modification to, any Permit listed or required to be listed in Section 3.10(b) of the Disclosure Schedule; (iii) neither

Seller nor Cytori UK has received any notice or other communication from any Governmental Authority or any other Person regarding (A) any actual, alleged, possible or potential violation of or failure to comply with any material term or requirement of any Permit listed or required to be listed in Section 3.10(b) of the Disclosure Schedule or (B) any actual, proposed, possible or potential revocation, withdrawal, suspension, cancellation, termination of or modification to any Permit listed or required to be listed in Section 3.10(b) of the Disclosure Schedule . . . . The Purchased Permits listed in Section 3.10(b) of the Disclosure Schedule collectively constitute all of the Permits used by Seller (or, as applicable, Cytori UK) to lawfully conduct and operate the Business in the Territory in the manner in which it currently is conducted" (APA, Section 3.10(b)) (emphasis added);

(vi) "All applications, notifications, submissions, information, claims, reports and statistics, and other data and conclusions derived therefrom . . . submitted to made to the U.S. Food and Drug Administration . . . or other Governmental Authority were . . . true, complete and correct in all material respects as of the date of submission and any legally necessary or required updates, changes, corrections or modifications to such applications, submissions, information, claims, reports or statistics have been submitted to the FDA and other Governmental Authorities" (APA, Section 3.10(c));

(vii) "[N]either Seller nor Cytori UK is aware, nor has it received notice, of any Action pending with respect to a violation by Seller or Cytori UK of the FDCA or other Law, and, to the Knowledge of Seller, there are no facts or circumstances existing that would reasonably be expected to serve as a basis for such an Action" (APA, Section 3.10(d));

(viii) "No Governmental Authority has commenced or, to the Knowledge of Seller, threatened to initiate any action to request the recall of any products produced thereunder,

nor has Seller or Cytori UK received any notice to such effect and, to the Knowledge of Seller, there are no grounds for such action;" (APA, Section 3.10(e)); and

(ix) "Except as set forth in Section 3.15 of the Disclosure Schedule, the Purchased Assets and the assets of Cytori UK (a) constitute all of the assets, tangible and intangible, of any nature whatsoever, used to operate (and to the Knowledge of Seller, necessary to operate) the Business in the Territory in the manner presently operated by Seller and Cytori UK, and as has been conducted in the past year, in the Territory . . ." (APA, Section 3.15).

32. Under Section 9.01 of the APA, "Buyer and its Affiliates, officers, directors, employees, agents, successors and assigns and their respective shareholders, directors, officers and employees . . . shall be indemnified, reimbursed and held harmless by Seller for and against all losses, damages, claims, costs, Taxes and expenses, interest, awards, judgments and penalties (including reasonable attorneys' and consultants' fees and expenses) suffered or incurred by them . . . arising out of or resulting from (a) any inaccuracy in or any breach of any representation or warranty made by Seller contained in this Agreement . . ." (APA, Section 9.02).

D. Lorem Discovers Plus's Misrepresentations

33. Approximately six months after closing of the APA, however, Lorem discovered that Plus's representations made concerning the CE certification status of its Cytori UK facility (or lack thereof), including the statements made by Plus in Section 3.10(b) of the Disclosure Schedule to the APA, were false and highly-misleading. In particular, on or about October 16, 2019, Lorem learned from third-party BSI that the CE certificates for the Deeside facility "do not exist and have been cancelled," that BSI "cannot reactivate certificate(s) that were cancelled," and that instead Lorem would need to undergo and complete an entirely "new certification process and additional audits."

34. To Lorem's great surprise and detriment, Lorem also learned in October 2019 that it would be required to obtain all new CE certificates pursuant to the new MDR standards. The deadline for obtaining the far simpler and more familiar MDD certification was still some months ahead, but BSI and other notified bodies were already booked straight through (due to the change-over) and were not accepting any new MDD applications. This resulted in Lorem being unable to correct the defect caused by Plus in a reasonable and efficient manner. Furthermore, if Plus had been honest at the time of contracting, and Lorem (assuming they then agreed to complete the transaction) began the process promptly in May of 2019, the result may have been very different and Lorem might have recertified the Cytori UK facility by the deadline of May 2020. As it was, however, due to Plus's deception, BSI informed Lorem that Lorem would be required to apply for MDR certification for which there was already a long queue, which as shown above is a far more time-consuming and expensive process than reactivating suspended CE certification under the MDD requirements. In fact, MDR regulations and implementation guidelines were not yet finalized, and remain in process today. If the CE certificates for Cytori UK had remained valid and effective (as promised), then Lorem could immediately have resumed exporting products to China and commenced critical regulatory and marketing activities in China and in Europe to broaden or seek additional claims for their products.

35. Without a valid CE certificate in place at the Cytori UK Deeside facility, Lorem was unable to produce product for shipment to China and other countries that the CE Certificates are recognized in, and Lorem was unable to utilize the Certificate to serve as the basis for application of Class II registrations for the products in China. This caused the full business development in China and the Asia Pacific region to be delayed by at least two and a half years. These certificates were the basis for all of the approvals that had existed and which were to be

sought in China. Furthermore, Lorem was required to discard all of the product purchased from Plus that was improperly exported to China. As a result, Lorem must maintain a very expensive business with operations costing millions of dollars annually (or suffer total catastrophic losses) without the ability to develop its primary market as intended. Lorem has also had to pay considerable funds to manage and then liquidate the Cytori UK facility, which due to Plus's deception became useless to the business.

E. Plus Breached the Representations and Warranties Made In the APA

36. As shown above, Plus has materially breached its representations and warranties in the APA that:

(i) Plus was "in good standing" and was authorized to "conduct its business as it is now being conducted" when in fact Plus was not in good standing and was not authorized to sell or export product shipments to China without a valid CE certificate in place;

(ii) Plus's books and records were "complete and accurate in all material respects" when in fact Plus's books and records were incomplete and inaccurate and did not truthfully disclose the critical facts that the CE certificates for its Deeside facility had been canceled, that the CE certificates could not be restored or reactivated, and that Lorem would instead have to restart the entire CE certification process over from scratch in a very challenging new regulatory scheme with great delays to the business;

(iii) Plus's business has been conducted "in the ordinary course of business" and that there has not been "any material loss" of any of the Purchased Assets when in fact Plus had not conducted its business in the ordinary course of business because Plus did not have valid CE certificates in place for Cytori Ltd. in Deeside and because Plus knowingly and illegally shipped products to China without a valid CE certificate in place;

(iv) Plus has "conducted its business in compliance with all applicable Laws or Governmental Orders" and "no event has occurred or circumstance exists that may constitute or result in a material violation" or failure to comply with any Law with respect to the Purchased Assets when in fact Plus did not comply with all applicable laws because it failed to maintain valid CE certificates for its Cytori Ltd. facility in Deeside, and because it knowingly shipped products to China without a valid Certificate of Free Sale, or a valid CE certificate in place, just days prior to the execution of the APA;

(v) Section 3.10(b) of the Disclosure Schedule contained a complete and accurate list of all Permits required for the Business when in fact Section 3.10(b) did not disclose that the CE certificates for the Cytori UK facility had been canceled and could not be reactivated and that instead the Cytori UK facility would have to restart the entire CE certification process over from scratch. Additionally, Plus breached its representations and warranties made in Section 3.10(b) of the APA in that the Disclosure Schedule omitted at least several other valid and material permits and licenses that were required to have been listed, including without limitation Cytori's Class II(a), II(b) and Class III Celase certifications for its San Diego facility (CE 568434 and CE 622786);

(vi) All submissions and information submitted to the FDA and/or any other governmental entity were "true, complete and correct in all material respects" when in fact Plus's submissions to governmental entities were not true and correct because Plus's CE certificates required for exporting products to China were no longer valid;

(vii) Plus is not aware of "facts or circumstances that would reasonably be expected to give rise to an action" against Plus for a violation of any law when in fact Plus was

acutely aware that its Deeside, UK facility was not CE compliant and that Plus violated export laws by shipping products from Deeside to China without a valid CE certificate in place;

(viii) "there are no grounds" for an action by any governmental entity to request the recall of any products produced under the APA when in fact Plus was aware of grounds for such an action because its Deeside facility was not CE compliant and Plus violated export laws by shipping products from Deeside to China without a valid CE certificate in place; and

(ix) the Purchased Assets are sufficient for the APA and "constitute all of the assets" used to operate the Business in the Territory when in fact Plus's Purchased Assets were not sufficient to operate the Business in the Territory because its Deeside facility lacked valid CE certificates and because Plus cannot operate its business or export products from the UK without valid CE certificates in place.

F. Plus Refuses To Indemnify Lorem For Its Losses

37. By letter dated October 15, 2020, Lorem's Chairman, Kian Thiam Lim, notified Plus that it had breached the representations and warranties in the APA by misrepresenting the status of the CE Certificate at Cytori UK as more fully alleged herein. Lorem demanded Plus indemnify it for certain losses arising out of or resulting from Plus's breaches of representations and warranties in the APA.

38. To date, Plus has failed and refused to indemnify Lorem for its losses.

First Cause of Action

Breach Of Contract

(Against Defendant Plus Therapeutics, Inc.)

39. Lorem incorporates by reference all preceding allegations of this complaint, as if set forth in full herein.

40. Lorem and Plus are parties to the APA dated March 29, 2019.

41. In the APA, Plus represented and warranted, among other things, that: (a) it was "in good standing under the laws of the jurisdiction of its incorporation" and was authorized to "conduct its business as it is now being conducted;" (b) its Books and Records were complete and accurate in all material respects; (c) it has conducted its business "in compliance with all applicable laws, and that there has not been any material loss or interruption of use of any of the Purchased Assets;" (d) it has "conducted and continues to conduct its business in accordance with all Laws and Governmental Orders applicable to the Business;" (e) the Disclosure Schedule contained a complete and accurate listing of all Permits required for the Business; (f) all submissions and reports it made to the FDA or other Governmental Authority were true and accurate; (g) it is not aware of any Action pending with respect to a violation of the FDCA or other Law and that "there are no facts or circumstances existing that would reasonably be expected to serve as a basis for such an Action;" (h) to its knowledge, no Governmental Authority has commenced or threatened any action to request the recall of any products … and, to the Knowledge of Seller, there are no grounds for such action; (i) the assets purchased by Lorem under the APA were sufficient; (j) only a routine audit was required to activate the CE Certification at Cytori UK; and (k) it would indemnify Lorem for any losses arising out of or resulting from any inaccuracy in or any breach of any representation or warranty made by Plus in the APA.

42. Lorem has performed all conditions, covenants, and promises required of it under the APA, except for those conditions, covenants, and promises which have been excused by the breach or non-performance of Plus.

43. Plus breached the APA and more specifically breached the representations and warranties in the APA by, among other things: (a) misrepresenting that Cytori UK was CE

Certified and in good standing under the applicable laws of its incorporation; (b) failing to provide Books and Records that were complete and accurate in all material respects; (c) failing to conduct its business in compliance with all applicable laws; (d) illegally conducting business by shipping products to China in March 2019 without a valid CE Certificate; (e) failing to provide a complete and accurate listing of all permits and licenses required for the business in the Disclosure Schedule; (f) failing to provide true and accurate submissions and reports made by Plus to the FDA or other Governmental Authority; (g) failing to disclose that the unlawful shipment to China in March 2019 was a fact or circumstance giving rise to a potential Action; (h) failing to indicate that the unlawful shipment to China in March 2019 was subject to recall; (i) improperly representing the sufficiency of the assets purchased by Lorem under the APA; (j) stating only a routine audit was required to activate the CE Certificate at Cytori UK; and (k) refusing to indemnify Lorem for losses arising out of or resulting from Plus's breaches of representations and warranties made in the APA.

44. As a direct and proximate result of Plus's failure to perform its contractual obligations, Lorem has been damaged in an amount to be proven at trial but in an amount of at least $6,000,000.

Second Cause of Action

Breach Of The Implied Covenant Of Good Faith And Fair Dealing

(Against Defendant Plus Therapeutics, Inc.)

45. Lorem incorporates by reference all preceding allegations of this complaint, as if set forth in full herein.

46. Lorem and Plus are parties to the APA dated March 29, 2019.

47. Lorem has performed all conditions, covenants, and promises required of it under the APA, except for those conditions, covenants, and promises which have been excused by the breach or non-performance of Plus.

48. Plus has unfairly interfered with Lorem's right to receive the benefits of the APA by, among other things, intentionally misrepresenting the CE Certification status of Cytori UK and depriving Lorem of the ability to sell and manufacture products at Cytori UK, and export such products to the UK, EU, and China.

49. The wrongful acts of Plus described herein, including but not limited to breaches of the APA, and the breaches of the implied covenant contained in the APA, were at all relevant times undertaken in bad faith.

50. As a direct and proximate result of Plus's conduct, Lorem has been damaged in an amount to be proven at trial but in an amount of at least $6,000,000.

Third Cause of Action

Fraudulent Inducement

(Against Defendant Plus Therapeutics, Inc.)

51. Lorem incorporates by reference all preceding allegations of this complaint, as if set forth in full herein.

52. As detailed supra, Plus knowingly and fraudulently made numerous material misrepresentations, both in writing, verbally, and in Section 3.10(b) of the Disclosure Schedule to the APA, that the Cytori UK facility's CE Certification was intact but for a customary overdue audit.

53. As alleged herein, Plus knew its representations and/or omissions were false and/or misleading when made.

54. Plus's misrepresentations and/or omissions were made with the intent to induce Lorem to rely on such misrepresentations and enter into negotiations regarding the APA, conduct due diligence, refrain from pursuing alternative commercial pursuits, and ultimately enter into the APA. Plus acted in this way because if it failed, then the company would likely have been dissolved by its lenders. It apparently accepted the risk of this litigation in the future to save the company at that time.

55. Lorem justifiably relied on Plus's representations regarding the CE certification status of the Cytori UK facility.

56. As a direct and proximate result of Plus's fraudulent conduct, Lorem has been damaged in an amount to be proven at trial, including expenses incurred in the negotiations and due diligence prior to the transaction, foregone opportunities, and the numerous consequences flowing from the APA, and in an amount of at least $6,000,000.

57. Plus's conduct was done willfully and intentionally, and in doing the acts herein alleged, Plus acted with oppression, fraud, and malice. Accordingly, Plus's conduct in conscious disregard of Lorem's rights justifies an award of exemplary and punitive damages.

Fourth Cause of Action

Negligent Misrepresentation

(Against Defendant Plus Therapeutics, Inc.)

58. Lorem incorporates by reference all preceding allegations of this complaint, as if set forth in full herein.

59. As detailed supra, Plus negligently made numerous material misrepresentations, both in writing, verbally, and in Section 3.10(b) of the Disclosure Schedule to the APA, that the Cytori UK facility's CE Certification was intact but for a customary overdue audit.

60. As more fully alleged herein, Plus's misrepresentations were made without reasonable grounds for believing them to be true, as Plus was apprised of the true and contradictory facts at the time Plus made these misrepresentations to Lorem.

61. Plus's misrepresentations and/or omissions were made with the intent to induce Lorem's reliance on such misrepresentations and/or omissions and which did thereby induce Lorem to enter into the APA.

62. Lorem justifiably relied on Plus's representations regarding the CE certification status of the Cytori UK facility at least because Plus had superior first-hand knowledge of the CE certification status of its own Cytori UK facility and also because, at the time they were made, Plus's representations and actions (including exporting product into China) were consistent with the valid and existing CE certificate for the Deeside facility on file in the Data Room up until the day before closing.

63. As a direct and proximate result of Plus's negligent misrepresentations, Lorem has been damaged in an amount to be proven at trial, including expenses incurred in the negotiations and due diligence prior to the transaction, foregone opportunities, and the numerous consequences flowing from the APA, and in an amount of at least $6,000,000.

DEMAND FOR JURY TRIAL

64. Plaintiff hereby demands a jury trial for all triable issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Lorem prays for relief as follows:

1. For compensatory damages, including expenses incurred in the negotiations and due diligence prior to the transaction, foregone opportunities, and the numerous consequences flowing from the APA, and operational costs and expenses in an amount to be determined at trial but in an amount of at least $6,000,000;

2. For prejudgment interest at the maximum rate allowed by law;

3. For punitive and exemplary damages according to proof;

4. For Lorem's attorneys' fees and costs incurred in this matter;

5. For such other relief as the Court deems just and proper.

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